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Jennifer Rishko

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Arien et al.	Confirmation No.:	4146
Appln. No.	:	10/522,456		
Filed	:	January 21, 2005		
Title	:	POLYMERIC MICROEMULSIONS		
Art Unit	:	1615		
Examiner	:	AHMED, HASAN SAYED		

MAIL STOP APPEAL BRIEF PATENTS
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

APPEAL BRIEF**i. Real Party in Interest**

The real party of interest is Janssen Pharmaceutica, NV, a corporation of Belgium.

ii. Related Appeals and Inferences

There are no related appeals and interferences known to the Applicants.

iii. Status of Claims

Claims 1, 2 and 12-15 are pending in this application. Claims 1, 2 and 12-15 have been finally rejected on January 23, 2009 and this Appeal is taken from those claims. Claims 24 and

25 were cancelled on January 21, 2005, claims 8-11, 16-23 and 26 were cancelled on March 18, 2008 and claims 3-7 were canceled on October 28, 2008.

iv. Status of Amendments

A Final Office Action rejecting claims 1, 2 and 12-15 was mailed on January 23, 2009. An Advisory Action maintaining the final rejection was mailed May 1, 2009. A Notice of Appeal was filed May 26, 2009 in response thereto. No amendment has been filed subsequent to the final rejection.

v. Summary of Claimed Subject Matter

Independent claim 1 is directed to a diblock copolymer of formula A-B wherein polymer block A represents a linear pharmaceutically acceptable hydrophilic polymer with a molecular weight <1,000, and polymer block B represents a polymer comprising at least two different monomers selected from glycolic acid, propiolactone, γ -butyrolactone, δ -valerolactone, γ -valerolactone, ϵ -caprolactone, trimethylene carbonate, p-dioxanone, tetramethylene carbonate, ϵ -lactone, 1,5-dioxepan-2-one wherein the diblock copolymer is liquid at a temperature below 50° C. (See, e.g., page 5, lines 15-23, page 8, lines 12-15; and page 10, lines 27-37). Dependent claim 2 is directed to a diblock copolymer according to claim 1 wherein polymer block B represents a polymer comprising monomers selected from glycolic acid, propiolactone, γ -butyrolactone, δ -valerolactone, ϵ -caprolactone, trimethylene carbonate, p-dioxanone, tetramethylene carbonate, ϵ -lactone, 1,5-dioxepan-2-one or mixtures thereof. (See, e.g., page 5, lines 15-23). Dependent claim 12 is directed to a diblock copolymer according to claim 1 having a molecular weight ranging from 2,000 to 10,000. (See, e.g., page 11, lines 1-11). Dependent claim 13 is directed to a diblock copolymer according to claim 12 having a molecular weight ranging from 2,000 to 8,000. (See, e.g., page 11, line 10). Dependent claim 14 is directed to a diblock copolymer according to claim 13 having a molecular weight ranging from 2,500 to 7,000. (See, e.g., page 11, line 11). Dependent claim 15 is directed to a diblock copolymer according to claim 1 being a liquid at room temperature or at 37 °C. (See, e.g., page 11, lines 30-31).

vi. **Grounds of Rejection to be Reviewed on Appeal**

The Examiner has finally rejected independent claim 1 and dependent claims 2 and 12-15 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,716,203 (“Casey et al.”). In particular, the final Office Action asserts:

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a diblock polymer comprising a linear, hydrophilic polymer block A and a polymer block B comprising at least two different monomers, as taught by Casey [et al.]. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful hydrogels for pharmaceutical compositions, as explained by Casey [et al.].

(Final Office Action of January 23, 2009 at pages 3-4).

vii. **Argument**

I. CLAIMS 1, 2 AND 12-15 STAND FINALLY REJECTED UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER CASEY ET AL. APPLICANTS RESPECTFULLY TRAVERSE AND THE REJECTION SHOULD BE OVERRULED.

As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007), the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Determining the scope and content of the prior art;
- (B) Ascertaining the differences between the claimed invention and the prior art;
- (C) Resolving the level of ordinary skill in the pertinent art;
- (D) Determining the obviousness or nonobviousness of the claimed subject matter.

Secondary considerations such as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. The question of obviousness must be resolved on the basis of these factual determinations. While each case is different and must be decided on its own facts, the

Graham factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis.

Casey et al. does not disclose or suggest the claimed invention. The claimed invention is directed to diblock copolymers of formula A-B wherein:

polymer block A represents a linear pharmaceutically acceptable hydrophilic polymer with a molecular weight <1,000, and

polymer block B represents a polymer comprising at least two different monomers selected from glycolic acid, propiolactone, γ -butyrolactone, γ -valerolactone, δ -valerolactone, ϵ -caprolactone, trimethylene carbonate, p-dioxanone, tetramethylene carbonate, ϵ -lactone, 1,5-dioxepan-2-one,

wherein the diblock copolymer is liquid at a temperature below 50°C.

Casey et al. discloses diblock copolymers having a first block of a polyalkylene oxide and a second block of glycolic acid ester and trimethylene carbonate linkages. See Abstract. Casey et al. does not disclose or suggest that the first block polymer has a molecular weight <1,000 as claimed. In fact, Casey et al. teach away from the claimed molecular weight by disclosing that “[i]n another embodiment, the number average molecular weight of the polyalkylene oxide block is from about 4,000 to 30,000.” (see col. 1, lines 47-50). A prima facie case of obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. In re Geisler, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).

Further, the only example of a diblock copolymer in Casey et al. regards use of PEG having a molecular weight of 5,000. The present specification, on the other hand, discloses that the claimed molecular weight, i.e., <1,000, is preferred. (See, e.g., page 10, line 29). The present specification also discloses that “[s]ince the polymers of the present invention are characterized by being liquid below 50° C., polymers with a limited molecular weight are preferred.” (See page 11, lines 1-2).

Casey et al. also does not disclose that the diblock copolymer is liquid at a temperature below 50 °C. Rather, Casey et al. discloses that “[t]he inherent viscosity of the copolymer, as measured at 30° C for a 0.5% (w/v) solution in chloroform or methylene chloride, is 0.25 to about 1.50 dL/g”, (See col. 2, lines 21-26). “Inherent viscosity” is defined as:

[A] viscometric method for measuring molecular size. [Inherent viscosity] IV is based on the flow time of a polymer solution through a narrow capillary relative to the flow time of the pure solvent through the capillary. The units of IV are typically reported in deciliters per gram (dL/g). IV is simple and inexpensive to obtain and reproducible between different laboratories.

(See excerpt from <http://www.absorbables.com/inherentviscosity.htm>, attached hereto). As stated in Casey et al., the inherent viscosity is measured when the polymer is in chloroform or methylene chloride, each a solvent in which the polymer is capable of dissolving. (See col. 2, lines 21-26). This does not mean that the polymer itself is liquid. As further evidence of this is the fact that the only example of a diblock copolymer in Casey et al. regards a composition having a melting temperature of 59° C. (See col. 14, lines 52-59).

Casey et al., which discloses that the diblock copolymers disclosed therein are useful as coating and lubricating finish for surgical articles (see , e.g., col. 1, lines 10-14), does not disclose the problem or the solution addressed by the claimed invention.

The specification discloses that the formation of aqueous solutions of drug loaded micelles is difficult and that complex or time-consuming methods are often required. (See, e.g., page 2, line 24 to page 3, line 13). The specification discloses that the claimed copolymers, which have self-emulsifying properties, are able to spontaneously form micellar solutions in water. (See, e.g., page 3, lines 15-25).

One skilled in the art could not have predicted that such relatively small copolymers would be able to form stable micelles based on the disclosure of Casey et al. Furthermore, one skilled in the art could not have predicted that the copolymers could very easily incorporate drugs, i.e., without the need to use complex techniques such as solvent evaporation or dialysis.

Reconsideration and withdrawal of the rejection of claims 1, 2 and 12-15 under 35 U.S.C. § 103 over Casey et al. are respectfully requested.

II. CONCLUSION

Because Casey et al. fails to disclose or suggest each element of the claimed invention, Applicants respectfully contend that there was no basis for a rejection of claims 1, 2 and 12-15 under 35 U.S.C § 103(a). Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of independent claim 1 and dependent claims 12-15 under 35 U.S.C § 103(a).

Payment

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Respectfully submitted,

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viii. Claims Appendix

1. (Previously Presented) A diblock copolymer of formula A-B wherein
polymer block A represents a linear pharmaceutically acceptable hydrophilic polymer with a molecular weight <1,000, and
polymer block B represents a polymer comprising at least two different monomers selected from glycolic acid, propiolactone, γ -butyrolactone, γ -valerolactone, δ -valerolactone, ϵ -caprolactone, trimethylene carbonate, p-dioxanone, tetramethylene carbonate, ϵ -lactone, 1,5-dioxepan-2-one wherein the diblock copolymer is liquid at a temperature below 50 °C.
2. (Original) A diblock copolymer according to claim 1 wherein polymer block B represents a polymer comprising monomers selected from glycolic acid, propiolactone, γ -butyrolactone, δ -valerolactone, ϵ -caprolactone, trimethylene carbonate, p-dioxanone, tetramethylene carbonate, ϵ -lactone, 1,5-dioxepan-2-one or mixtures thereof.
12. (Previously Presented) A diblock copolymer according to claim 1 having a molecular weight ranging from 2,000 to 10,000.
13. (Original) A diblock copolymer according to claim 12 having a molecular weight ranging from 2,000 to 8,000.
14. (Original) A diblock copolymer according to claim 13 having a molecular weight ranging from 2,500 to 7,000.
15. (Previously Presented) A diblock copolymer according to claim 1 being a liquid at room temperature or at 37° C.

ix. **Evidence Appendix**

Excerpt from <http://www.absorbables.com/inherentviscosity.htm>.

x. **Related Proceedings Appendix**

None.

xi. Figure Appendix

None.